

12-20-99

7

REV. 11/98  
For Other Than A Small Entity

Attorney Docket No. 3581/004

Applicants : Pat L. Gordon  
For : GASTRIC STIMULATOR APPARATUS AND METHOD  
FOR USE

EXPRESS MAIL CERTIFICATION

"Express Mail" mailing label number EI187446600US.

Date of Deposit December 17, 1999.

I hereby certify that this transmittal letter and the other papers and fees identified in this transmittal letter as being transmitted herewith are being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 C.F.R. § 1.10 on the date indicated above and are addressed to the Hon. Assistant Commissioner for Patents, Washington, D.C. 20231.

*Claire S. Samuel*

Hon. Assistant Commissioner  
for Patents  
Washington, D.C. 20231

New York, New York  
December 17, 1999

TRANSMITTAL LETTER FOR UNEXECUTED  
ORIGINAL PATENT APPLICATION

Sir:

Transmitted herewith for filing are the  
[X] specification; [X] claims; [X] abstract; [X] unexecuted  
declaration, for the above-identified patent application.

Also transmitted herewith are:

[X] 9 sheets of:

[ ] Formal drawings.

[X] Informal drawings. Formal drawings will be filed  
during the pendency of this application.

[ ] Certified copy(ies) of application(s)

12/17/99  
JC600 U.S. PTO

JC675 U.S. PTO  
09/466387  
12/17/99

\_\_\_\_\_  
(country) (appln. no.) (filed)

\_\_\_\_\_  
(country) (appln. no.) (filed)

\_\_\_\_\_  
(country) (appln. no.) (filed)

from which priority is claimed.

[ ] An assignment of the invention to \_\_\_\_\_.

[ ] A check in the amount of \$40.00 to cover the recording fee.

[ ] Please charge \$40.00 to Deposit Account No. 06-1075 in payment of the recording fee. A duplicate copy of this transmittal letter is transmitted herewith.

[ ] An associate power of attorney.

The filing fee has been calculated as shown below:

FOR	NUMBER FILED		NUMBER EXTRA		RATE	FEE
BASIC FEE						\$760.00
TOTAL CLAIMS	67	- 20 =	47	X	\$18	\$846.00
INDEPENDENT CLAIMS	6	- 3 =	3	X	\$78 =	\$234.00
[ ] MULTIPLE DEPENDENT CLAIMS					+ \$260 =	\$
					TOTAL	<u>\$1840.00</u>

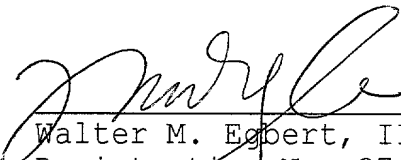
[ ] A check in the amount of \$\_\_\_\_\_ in payment of the filing fee is transmitted herewith.

[X] This application is being filed unaccompanied by a filing fee. The appropriate filing fee will be paid in response to a Notice to File Missing Parts, pursuant to 37 C.F.R. § 1.53(d).

[X] The Commissioner is hereby authorized to charge payment of any additional filing fees required under 37 C.F.R. § 1.16, in connection with the paper(s) transmitted herewith, or credit any overpayment of same, to deposit Account No. 06-1075. A duplicate copy of this transmittal letter is transmitted herewith.

[ ] Amend the specification by inserting before the first line the sentence: -- This is a [ ] continuation-in-part, of application Serial No.: \_\_\_\_\_, filed  
entitled \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_.

[ ] Please charge \$\_\_\_\_\_ to Deposit Account No. 06-1075 in payment of the filing fee. A duplicate copy of this transmittal letter is transmitted herewith.

  
\_\_\_\_\_  
Walter M. Egbert, III  
Registration No. 37,317  
Attorney for Applicants

FISH & NEAVE  
1251 Avenue of the Americas  
New York, New York 10020-1104  
Tel.: (212) 596-9000

GASTRIC STIMULATOR  
APPARATUS AND METHOD FOR USE

This application claims the benefit of U.S. Provisional application Serial No. 60/129,209, filed April 14, 1999, which is incorporated by reference in  
5 its entirety herein.

Background of the Invention

This invention relates to electrical stimulation apparatus and methods for use in stimulating body organs, and more particularly to  
10 implantable apparatus and methods for periodic electrical gastric stimulation.

The field of electrical tissue stimulation has recently been expanded to include devices which electrically stimulate the stomach with electrodes  
15 implanted in the tissue. These gastric stimulators have been found to successfully combat obesity in certain studies. Medical understanding as to how this treatment functions to reduce obesity is currently incomplete. However, patients successfully treated  
20 report achieving normal cycles of hunger and satiation.

An apparatus and treatment method for implementing this therapy was described in U.S. Patent No. 5,423,872 to Dr. Valerio Cigaina, which is hereby

incorporated by reference in its entirety herein. The apparatus described in the Cigaina patent stimulates the stomach antrum pyloricum with trains of stimulating pulses during an interval of about two seconds followed by an "off" interval of about three seconds.

5           Current pacemaker design incorporates a number of features useful for the type of tissue or organ being stimulated. Pacemakers stimulating cardiac or neurological tissue, for example, may typically contain an accurate, drift-free crystal oscillator to  
10 carry out real-time functions such as pulse generation. In particular, some cardiac pacemakers use a time reference to keep track of the time-of-day with a 24-hour clock in order to log data or to vary pacing parameters during the 24-hour cycle. Similarly,  
15 neurological stimulators, such as a neurological stimulator manufactured by Cyberonics, may use the time-of-day as a reference to deliver one or more periods of pulse-train stimulation (typically lasting a few minutes each) to the vagus nerve to treat epilepsy.

20           The design and operation constraints for a gastric pacemaker, or stimulator, are substantially different from those for a cardiac pacemaker or a neurological pacemaker, for example. With a gastric stimulator for weight loss, size is less of a concern  
25 because of the large anatomy associated with obesity. However, a long operating life for an implantable device remains an important feature, given the significantly higher current drain required by this therapy compared to cardiac pacing. Since the  
30 implantable pulse generator may be located subcutaneously in the abdominal wall, it is feasible to

use a larger device, including a larger, longer-life battery.

Moreover, stomach stimulation may require different levels and cycles of stimulation than that required for cardiac stimulation or nerve stimulation.

5 In a neuromuscular stomach generator, for example, power consumption can be five to seven times higher than for a cardiac pacemaker. Maintaining the proper energy level for stimulation may place energy demands on the life of the battery. The characteristics of  
10 entrainment of the stomach tissue may require cycling of the electrical stimulation in more complex schedules than that previously required. Observations of early human implants have shown a surprising increase in the impedance of the electrode tissue interface, from about  
15 700 ohms at time of implant to 1300 ohms after only as much as three months of implants. With constant current and increased impedance, voltage drain on the battery may be unacceptably high.

Thus, there is a need to optimize the  
20 operation of gastric pacemakers, or stimulators, so as to provide a longer life for the device, and hence, a longer duration of therapy without the need for repeated surgical procedures.

It is an advantage to provide an apparatus  
25 and method of stimulation wherein voltage or current can be controlled to extend the useful life of a battery used therein.

It is also an advantage of the invention to provide an apparatus and method of stimulation that is  
30 able to calculate and store data parameters to improve

the levels of stimulation based on operating conditions.

It is a further advantage of the invention to provide a clock function which allows the stimulation cycles of the tissue to be programmed and executed on  
5 long term basis.

#### Summary of the Invention

These and other advantages of the invention are accomplished by providing apparatus and methods for stimulating neuromuscular tissue of the  
10 gastrointestinal tract by applying an electrical pulse to the neuromuscular tissue. The electrical pulse applied to the tissue may be a current-controlled pulse or a voltage-controlled pulse as deemed appropriate by one skilled in the art. In the case of a stimulator  
15 applying a current-controlled pulse, the stimulator may include a voltage sensor to sense the voltage across the neuromuscular tissue being stimulated. A voltage threshold is determined by the circuitry. In a preferred embodiment, the voltage threshold may be  
20 adjustable and may be a function of the level of current applied to the tissue being stimulated.

The circuitry compares the sensed voltage and the predetermined voltage threshold. If the sensed voltage is found to meet or to exceed the predetermined  
25 voltage threshold, the circuitry will adjust the current-controlled pulse such that the sensed voltage does not exceed the predetermined voltage threshold. In a preferred embodiment, this may be accomplished by generating an error signal between the sensed voltage  
30 and the voltage threshold by using negative feedback control. The occurrence of the sensed voltage meeting

or exceeding the predetermined voltage threshold may be stored as an "event", along with time at which the event occurred during the pulse interval and/or during the treatment period.

The circuitry also provides the capability of  
5 utilizing the data that is obtained during the sensing and feedback functions. For example, the total impedance may be calculated from the voltage and current values. One component of the impedance may be the electrode resistance, and the second component may  
10 be the polarization capacitance. The electrode resistance may be obtained by dividing the voltage by the controlled current. The capacitance may be obtained from the current divided by the time rate of change of the voltage. The calculated values of the resistance  
15 and the capacitance may be stored on a memory device or displayed on a display device, or used in the feedback process to determine the increment of adjustment to the current-controlled pulse.

The neuromuscular stimulator may also include  
20 a real time clock and a programmable calendar for tailoring the stimulating waveform parameters over the treatment period. The real time clock supplies data corresponding to the time of day during the treatment period. The programmable calendar stores parameters  
25 which refer to the shape of the stimulating waveform. Each of the parameters may be referenced directly or indirectly to the time of day. Circuitry, such as a control circuit, applies the stimulating pulses which are defined by the parameters at the appropriate times  
30 of the day during the treatment period.



In a preferred embodiment, the parameter may be a time period during which the electrical pulses are applied. The time period may be defined by a start time and a duration. When the time period is so defined, the circuit may apply the stimulating pulse beginning at the start time and continuing for the specified duration. The time period may alternatively be defined by a start time and a stop time. In such a case, the circuit applies the stimulating pulse beginning at the start time, and continues to apply the pulses until the stop time. According to another embodiment, the time period may be defined by a start time, a first duration with respect to the start time, and a second duration with respect to the first duration. The circuit may apply the stimulating pulse beginning at the start time and continuing for the first duration, and subsequently discontinuing the pulses during the second duration. Additional parameters may be a time period corresponding to the pulse width for each pulse during the series of electrical pulses, and a time period corresponding to the pulse interval between each pulse. A parameter may also include a voltage corresponding to the pulse height for each pulse in the series of electrical pulses.

The real time clock and the programmable calendar allow the stimulating waveform to vary over greater periods of time. For example, the real time clock may supply data corresponding to a week during the time period. Consequently, the waveform may be programmed to apply a different waveform during each particular week in the treatment period. The real time

clock may also supply data corresponding to the day of the week during the treatment period. Alternatively, the real time clock may supply data corresponding to a month of the year during the treatment period, such that the waveform may vary from month-to-month as the treatment progresses. Moreover, the real time clock may also supply data corresponding to the day of the month, and/or the day of the year.

Although current-controlled stimulating pulses are described above, the invention is equally applicable to constant voltage and voltage-controlled pulses.

Further features of the invention, its nature and various advantages will be more apparent from the accompanying drawings and the following detailed description of the preferred embodiments.

#### Brief Description of the Drawings

FIG. 1 is a simplified view of a preferred embodiment in accordance with the invention.

FIG. 2 is a simplified schematic view of a component of the apparatus of FIG. 2 in accordance with the invention.

FIG. 3 is a simplified schematic view of a component of the apparatus of FIG. 3 in accordance with the invention.

FIG. 4 is a flow chart of steps involved in creating a table of voltage threshold values and associated current values in accordance with the invention.

FIG. 5 is a flow chart of steps involved in comparing sensed voltage values with voltage threshold values in accordance with the invention.

FIG. 6(a) is a time plot illustrating a current wave form in accordance with the invention.

FIG. 6(b) is a time plot illustrating a prior art voltage wave form corresponding to the time plot of FIG. 6(a).

5           FIG. 6(c) is a time plot illustrating a voltage wave form corresponding to the time plot of FIG. 6(a) in accordance with the invention.

FIG. 7 illustrates a data structure for storing parameters for the waveform of a stimulating  
10 pulse in accordance with the invention.

FIG. 8 illustrates another data structure in accordance with the invention.

FIG. 9 illustrates yet another data structure in accordance with the invention.

15   Detailed Description of the Preferred Embodiments

          An improved neuromuscular stimulator is illustrated in FIG. 1, and designated generally with reference number 10. The stimulator 10 includes an implantable pulse generator 12, a lead system 14 of one  
20 or more electrodes 16. Stimulator 10 may use voltage controlled and/or current controlled stimulation in such a way to limit power drains from the battery and to allow accurate determination of total impedance, including lead resistance and polarization capacitance.  
25 Consequently, maintaining substantially consistent levels of power consumption may dramatically improve longevity. Stimulator 10 may limit changes in power consumption and may store data, which may be provided to the clinician or used to vary stimulation  
30 parameters. For example, stored data may include the occurrences of a voltage and/or current limitation

during a stimulation pulse. Measured parameters may be stored to correlate stimulation levels with operating conditions in order to maintain consistent power consumption, as will be described in greater detail hereinbelow.

5           The implantable pulse generator 12 provides a series of electrical pulses to the stomach S. The implantable pulse generator 12 may be surgically implanted subcutaneously in the abdominal wall. The electrodes 16 may be installed in contact with the  
10 tissue of the stomach. Electrodes may be positioned on the outer surface of the stomach, implanted within the stomach wall, or positioned on the inner surface of the stomach wall. For example, the electrodes may be attached to the tissue by an electrocatheter as  
15 described in Cigaina patent 5,423,872, incorporated by reference above. Alternatively, the electrodes may be as described in copending U.S. Application PCT/US98/1042 filed on May 21, 1998, and copending application 09/122,832, filed July 27, 1998, both of  
20 which are incorporated by reference in their entirety herein. As yet another alternative, electrodes may be substantially as described in concurrently filed application no. \_\_\_\_/\_\_\_\_ (Docket 3581/05) and application no. \_\_\_\_/\_\_\_\_ (Docket 3581/06),  
25 both of which are incorporated by reference in their entirety herein.

A preferred embodiment of a current-controlled and/or voltage-controlled stimulator circuit according to the present invention is illustrated in  
30 FIG. 2, and hereinafter referred to as I/V circuit 20. I/V circuit 20 may typically be housed in implantable

pulse generator 12. I/V circuit 20 may limit power drains from the battery 22 and allow accurate determination of total impedance, including lead resistance and polarization capacitance.

The I/V circuit 20 also includes a control  
5 circuit 24, a voltage multiplier 26, storage capacitor 28, a regulated switch 32, and a voltage and/or current sensor and feedback controller 34 to regulate switch 32. The stomach tissue stimulation occurs on leads 14, which are in turn connected to  
10 electrodes 16 (FIG. 1). Moreover, memory 25 may be provided to store data, and display unit 27 for displaying data may be provided.

The battery 22 may be selected in order to have long life characteristics when implanted in the  
15 patient. The voltage-control and current-control features of the invention may extend battery life further. Preferably, the battery 22 has deliverable capacity of greater than 2.5 amp-hours. In a preferred embodiment, two batteries may be provided.

20 The regulated switch 32 is designed to control current and/or voltage levels either throughout the entire output stimulator pulse, e.g., by using continuous feedback, or only at the leading edge, e.g., by selecting the appropriate initial voltage on  
25 capacitor 28 based on  $V_c = V_{\text{control}}$  or  $V_c = I_{\text{control}} \cdot R_{\text{electrode}}$ .

The shape of the current and/or voltage waveform applied to the stomach tissue is adjustable and controlled by digital means in the control circuit 24, which typically is or contains a microprocessor.

30 The timing features of control circuit 24 are illustrated in FIG. 3. By using a crystal 40 to

control oscillator 42 (which is either internal or external of processor 44 which may receive input 43 from control circuit 24 or provide output 45), accuracy is achieved for real-time clock counter 46.

Alternatively, the oscillator 40 and count down chain  
5 can also be external to processor 44 and also be used to generate the stimulating waveform. Typically, a 32 or 100 kilohertz crystal clock may be used to provide timing. Stimulation pulse width is typically 100 to 500  
10 microseconds (10 to 50 oscillations of 100 kilohertz clock), and the pulse interval may be 25 milliseconds or 2500 oscillations. The "on time," i.e., the period in which the pulses are applied, may be two seconds (200,000 oscillations) for this waveform, and the "off  
15 time," i.e., the period in which no pulses are applied, may be three seconds. It is useful to synchronize time inside the processor 44. A programmable storage device, such as programmable calendar 48, may be used to keep track of different times during the treatment period, such as hours of the day, day of the week, etc.

20 With continued reference to FIG. 2, the electrodes 16 (FIG. 1) present an impedance to the stimulating output leads 14 of I/V circuit 20. This impedance may be made up of two components. The first component is a resistance due to net energy transfer  
25 from circuit 20 to the stimulated tissue S, and the second component is a capacitance in series with the resistance due to ion transfer and charge accumulation across the electrode-tissue interface. FIGS. 6(a)-(c) illustrate the effects of these components. If a pulse  
30 of constant current is sent through electrodes 16, as illustrated in FIG. 6(a), the resistance component

causes a voltage to immediately appear across the electrodes (FIG. 6(b)). As the current continues to flow during the pulse, the capacitance component charges up, which may contribute to a steady increase in voltage during the pulse. Both of these components  
5 may vary in value from patient to patient. For an individual patient, these values may also change after implantation due to factors such as, for example, location of electrode placement, shifts in placement, changes in physiological conditions at the tissue  
10 interface, changes in anatomical shape, etc.

For instance, an increase in capacitance may cause the voltage near the trailing edge of the constant current pulse to increase without any corresponding increase in stimulating strength. This  
15 in turn may cause increased energy to be delivered during the pulse, and thus a higher battery energy drain. In the case of a voltage pulse, a decrease in resistance may cause an increase in current at the leading edge of the pulse and attendant increased  
20 battery energy drain. Thus, the battery energy drain is limited in accordance with the invention by limiting the current and/or voltage during the stimulating pulse.

In a voltage pulse, which is typically  
25 generated by charging capacitor 28 to a peak value and turning on switch 32 to its maximum conductance, the initial peak current drain is only limited by switch conductance in series with the conductance of the lead system conductors 14.

30 I/V circuit 20 is capable of limiting high battery energy drain due to shifts in impedance. The

closure of output switch 32 is controlled by  
sensor/controller unit 34. In the preferred  
embodiment, sensor/controller unit 34 provides a novel  
feature of sensing both the voltage across and the  
current through switch 32. Instructions on the shape  
5 and duration of the stimulating waveform are received  
from control circuit 24. The feedback controller in  
sensor/controller unit 34 compares the actual current  
341 and/or voltage 342 of switch 32 to the wave shape  
instructions of control circuit 24. Based on the  
10 difference of these two signals, control circuit 24  
produces an error signal to control switch 32 through  
negative feedback. These operations can be  
accomplished in either a digital or analog mode or in a  
combination thereof. The switch 32 is typically an  
15 analog device, and therefore signal 343, which is  
ultimately produced to control switch 32, may also be  
analog. The digital portion of this function could be  
accomplished in control circuit 24 with real-time  
digitized current and/or voltage data 261 supplied by  
20 sensor/controller unit 34.

Another feature of switch 32 working in  
conjunction with control circuit 24 is the ability to  
detect when the pulse wave form meets or exceeds a  
certain limit, or threshold, in voltage and/or current,  
25 to flag that occurrence as an "event," and to log or  
store the event at the time in which it occurred. This  
event marker, along with the time during the waveform,  
is available to control circuit 24 via line 261.  
Control circuit 24 may also be programmed to detect  
30 when the limit, or threshold, is reached during a



particular part of the stimulating pulse, i.e., leading edge, trailing edge, etc.

Another feature in accordance with the present invention embodied in I/V circuit 20 is improved accuracy in the operation of voltage multiplier 26. An important novel feature is the added programmable parameter of a voltage and/or current limit or threshold value set by the clinician, in conjunction with the programmable value of either current or voltage, including the shape of the stimulating pulse (e.g., starting current and/or voltage, ending current and/or voltage, start time, stop time, duration, etc.)

The programmable current or voltage threshold parameter is stored with other programmable information in control circuit 24. An instruction based on this parameter is supplied to voltage multiplier 26 which is capable of charging capacitor 28 to a large number of voltages closely spaced in value. For example, the voltage multiplier 26 would be instructed by control circuit 24 to charge capacitor 28 to a voltage just slightly larger than the programmable voltage limit or threshold. The voltage multiplier 26 may also be used to control the wave shape in conjunction with sensor/controller unit 34.

The processor in control circuit 24 can adjust the voltage multiplier 26 to a lower voltage to achieve the programmed limiting and thus save battery power. The voltage multiplier 26, which may include a switch capacitor array, may increase or decrease the battery voltage  $V_B$ , e.g., in integer or half integer multiples thereof, such as  $1/2 V_B$ ,  $3/2 V_B$ ,  $2 V_B$ ,  $3 V_B$ ,

etc. Alternatively, voltage multiplier 26 may be or may contain a transformer, usually in flyback mode, to change battery voltage  $V_B$  in order to maintain the necessary voltage, e.g., such that  $V_m > I_{\text{program}} * R_{\text{electrode}}$ .

The embodiment of I/V circuit 20 allows for  
5 many programmable modes of operation including the modes of constant current and voltage discharge with switch 32 turned on to maximum conductance. One of the additional modes includes a constant current or a controlled-current wave shape with a separately  
10 programmable voltage limit or threshold. In this mode, the sensed current 341 may be used to regulate switch 32 through negative feedback. For example, the sensed voltage 342 is compared to the programmable voltage limit. If this sensed voltage 342 reaches this  
15 programmable voltage limit, the feedback may be modified to maintain the sensed voltage 342 at this limit. It is understood that the feedback may maintain the voltage at the limit, slightly below the limit, or prevent the voltage from exceeding the limit, as deemed  
20 appropriate by one skilled in the art. Another mode of operation is a constant voltage or controlled-voltage wave shape with a separately programmable current limit. In this mode, the sensed voltage 342 may be used to regulate switch 32 with negative feedback. The  
25 sensed current 341 is compared to the programmable current limit. If this sensed current 341 reaches the limit, the feedback may be modified to maintain current at this limit. Typically, the initial voltage on capacitor 28 may be set by control circuit 24 to be the  
30 minimum voltage required. For instance, if the constant current pulse is programmed to 10 milliamps

and the greatest total impedance is 700 ohms, the initial voltage of capacitor 28 would be set at a voltage slightly above seven volts such that the voltage across capacitor 28 at the end of the pulse would be seven volts.

5                Certain modes of operation in accordance with the invention may not require the use of particular elements described in I/V circuit 20 with respect to FIG. 2. For example, in the case of constant current or a current-controlled wave shape, voltage limiting  
10 may also be achieved without voltage sensing means in control circuit 24 by charging capacitor 28 to the programmed voltage limit value. A limitation in voltage is achieved since the voltage across 28 is theoretically the maximum voltage that can appear  
15 across output 14. In this case, event detection (as described above) can be implemented by detecting saturation or the condition of maximum conductance of switch 32. In the case of voltage discharge with switch 32 turned on to maximum conductance, no voltage  
20 regulation is taking place and therefore the voltage sensing of 24 is not necessary. However, current sensing is implemented to limit current in this case.

              Another feature of the preferred embodiment of I/V circuit 20 is the ability of a stored program or  
25 subroutine in control circuit 24 to generate a sequence of current-controlled (and/or voltage-controlled) pulses associated with a sequence of voltage (and/or current) limit values, to interpret resulting limit event data, and to thereby measure the induced voltage  
30 (and/or current) waveform shape. The I/V circuit 20 may store this shape for subsequent telemetry to the

clinician, and analyze the shape to calculate impedance values, including resistance and/or capacitance components, as will be described in greater detail hereinbelow.

An additional aspect in accordance with the invention is the minimum energy capacity of battery 22. To achieve long term therapy, e.g., for a three to five year period, the energy limiting features described above are preferably combined with at least a 10 watt-hr total battery capacity. In the case of lithium type batteries the corresponding total deliverable current should preferably be three ampere hours.

The operation of I/V circuit 20 is described with respect to FIGS. 4, 5, and 6(a)-6(c). FIG. 4 illustrates a method for setting the values of the upper limit voltage  $V_{max}$ . As a result of performing the steps of FIG. 4, a data table associating current values with upper voltage limits or thresholds  $V_{max}$  is compiled. The real-time clock is programmed to apply controlled-current values to the tissue at particular times during the treatment period. Upon implantation of the stimulator, the voltage for each programmed current value may be measured, and a voltage limit may be set for each current value. At step 50, an initial test voltage limit is set, i.e.,  $V_{lim}$ . The current-controlled or constant current pulse is applied at step 52. If the voltage is found to meet or exceed  $V_{lim}$  at step 54, the process proceeds to step 56.  $V_{max}$  may be set equal to  $V_{lim}$ . Alternatively,  $V_{max}$  is calculated as a value greater than the measured  $V_{lim}$ , e.g., 125% to 150% of the measured value. The calculated value of  $V_{max}$  is stored, preferably in tabular form along with the

associated current value, at step 56. If the voltage does not meet or exceed the present value of  $V_{lim}$  at step 54, then  $V_{lim}$  is reduced by a predetermined increment at step 58, and the process is repeated until the voltage exceeds the value of  $V_{lim}$ . This process is  
5 repeated for each current-controlled pulse value until all applicable values of  $V_{max}$  are calculated and stored in a table. Alternatively, this process may be carried out for a voltage-controlled pulse in order to create a table of associated current limits. In such a case, an  
10 initial value of a test current limit would be set at step 50, and the voltage-controlled pulse applied at step 52. The sensed current would be compared with the test current limit at step 54. If the sensed current is found to meet or exceed the test current limit, a  
15 current limit may be set at step 56. If the sensed current does not meet or exceed the test current limit, the test current limit may be lowered at step 58, and the process of steps 52-58 repeated. This procedure for setting a table of current/voltage limits is  
20 exemplary only, and it is contemplated that other test procedures may be implemented.

FIG. 5, in conjunction with FIGS. 6(a)-6(c), illustrates the operation of the I/V circuit 20 in accordance with the invention during the application of  
25 a stimulation waveform to the tissue. The following exemplary procedure is described with respect to a current-controlled pulse with a programmed voltage threshold, but a similar procedure would be carried out for a voltage-controlled pulse with a current  
30 threshold.

At step 60, the current-controlled pulse may be applied to the stomach tissue. The sequencing of various electrical pulses is controlled by the control circuit 24, described above with respect to FIG. 2. As illustrated in a time plot in FIG. 6(a), the exemplary  
5 current pulse commences at  $t_1$  and ends at  $t_2$ . (The durations of the various signals are not shown to scale and may have whatever duration is deemed appropriate to one skilled in the art.) Current-control switch 32 maintains current at the programmed current 64.

10 At step 62, a value is set for an upper voltage limit, i.e.,  $V_{\max}$ . The value of  $V_{\max}$  may be fixed. Alternatively,  $V_{\max}$  may be adjustable or programmable based on the circuit operating conditions, such as, for example, the magnitude of the current  
15 applied at step 60. A lookup of the tabular data compiled in FIG. 4 may be performed to set a value of  $V_{\max}$ .

At step 66, the sensor/controller unit 34 measures sensed voltage and determines whether the  
20 voltage meets or exceeds the upper voltage limit  $V_{\max}$ . The sensor/controller unit 34 may be programmed to measure continuously or periodically store voltage data telemetry at step 66. A time plot illustrating voltage  $V$  across the tissue is shown at FIG. 6(b). Due to the  
25 polarization capacitance effect of the stomach tissue, the voltage across the stomach tissue increases as the circuits attempts to maintain constant current. Thus, the voltage, initially at voltage 68 at  $t_1$ , may increase to voltage 70 at  $t_2$ . (FIGS. 6(a)-6(c) are  
30 aligned such that signals represented in the FIGS. in the same horizontal position occur simultaneously.)

In FIG. 6(b), the voltage meets or exceeds voltage limit  $V_{\max}$  72 at  $t_3$ .

The comparison of the voltage with the voltage limit  $V_{\max}$  (step 66) may occur continuously during the stimulating pulse. Alternatively, the voltage sensor 34 may be programmed to compare the voltage with the voltage limit  $V_{\max}$  at the leading edge of the stimulating pulse, i.e., at a time period near  $t_1$ . According to another alternative embodiment, the voltage sensor 34 may be programmed to determine if the voltage meets or exceeds  $V_{\max}$  at the trailing edge of the stimulating pulse, i.e., at a time period near  $t_2$ .

If the voltage limit sensor 34 is not triggered, i.e., voltage is below voltage limit  $V_{\max}$ , operation of the circuit proceeds on path 74 of the flowchart of FIG. 5, and the circuit applies a current pulse to the tissue, as required by the control circuit. Voltage limit  $V_{\max}$  may be set to a new value at step 62 if operating conditions require, e.g., if the current pulse changes.

However, if the voltage meets or exceeds voltage limit  $V_{\max}$ , several operating steps may also occur. Steps 76, 78, 80, and 82 are illustrated in sequential order. However, it is understood that steps 76, 78, 80, and 82 are independent and may occur in a different order or simultaneously, as deemed appropriate by one skilled in the art. Certain ones of these steps may also be omitted, if desired to change the functionality of the circuit.

At step 76, the occurrence of the "event" described above, i.e., the occurrence of voltage meeting or exceeding the upper voltage limit  $V_{\max}$  is

stored, e.g., in the memory of the control circuit. In the example of FIG. 6(b), the event occurred at time t3. The time associated with the event may be measured as an absolute time value, i.e., the calendar date and time, or as the elapsed time from the initiation of the treatment, or as the elapsed time from the initiation of the particular current pulse. The occurrence of the event may be included in telemetry data, as with the voltage data at step 66, above. The event data point may include the current value and the voltage at the time the event occurred, i.e., a "current value - voltage limit pair."

With continued reference to FIG. 5, data may be calculated at step 78. For example, the total lead resistance  $R_{eff}$  may be calculated, for example, as the ratio of  $V_{max}$  divided by the programmed current ( $I_{prog}$ ). The event data point may also include associating the current value with the electrode lead resistance, i.e., as an "electrode resistance pair." This data point may also be stored in the telemetry data. Monitoring lead resistance is useful in predicting the battery life of the stimulator. As described above, increased resistance causes a substantial voltage drain on the battery, with associated reduction in battery life.

The polarization capacitance may also be calculated from the data taken during the above steps. For example, the polarization capacitance may be calculated as the ratio of the programmed current to the time rate of change of the voltage (i.e.,  $C_{polarization} = I_{prog} / dV/dt$ ). From the parameters being measured, the time rate of change of the voltage may be approximated from the change in voltage between the



voltage 68 at the leading edge  $t_1$  and the voltage 70 at the trailing edge  $t_2$  of the pulse and the time elapsed during the pulse, or the pulsewidth (i.e.,  $t_2 - t_1$ ).

Calculation of the polarization capacitance provides information on battery drain, wherein a large

5 capacitance may be indicative of high drain on the battery that reduces battery life. The event data point may also include associating the current value with the polarization capacitance. This data point may also be stored in the telemetry data.

10 At step 80, voltage may be adjusted by using the voltage multiplier 26. For example, the control circuit 24 may be programmed to adjust the voltage multiplier 26 to reduce voltage in integer or fractional integer increments. With reference to FIG.  
15 6(c), after the event occurs at  $t_3$ , the voltage is adjusted to remain at the level of voltage limit  $V_{\max}$  72, slightly below voltage limit  $V_{\max}$  72, or not to exceed  $V_{\max}$  72.

The calculation of lead resistance and  
20 polarization capacitance at step 78 may be helpful in determining the degree of voltage adjustment in order to maintain the voltage below  $V_{\max}$ . A large value of electrode resistance or polarization capacitance may indicate a substantial drain on the battery.  
25 Accordingly, a substantial adjustment may be made in the voltage at step 80. Conversely, smaller values of electrode resistance or polarization capacitance may indicate a less substantial drain on the battery, and a smaller adjustment to keep the voltage at or below  $V_{\max}$ .

30 At step 82, the event data stored or calculated at steps 76-80 may be graphically displayed

or listed on a display terminal or printed output. The process may continue until it is determined that the treatment is completed at step 84, at which time the current/voltage limitation may be ended (step 86).

As illustrated in FIG. 3, above, I/V Circuit  
5 20 includes a real-time clock 46, which supplies data corresponding to the time of day during the treatment period, and programmable calendar 48, that can be programmed to store the parameters that define the above pulse train. The parameters are used by the  
10 control circuit 24 in determining the wave shape of the stimulating pulse. The parameters correspond to particular times during the treatment. Medical observations suggest that food intake, digestion and other gastrointestinal functions are circadian, that  
15 is, they operate on a 24 hour daily cycle. There are certain periods during the day when gastric functions are less active than other times of the day. The programmable calendar 48 can therefore provide increased stimulation at certain hours of the day, and  
20 decreased stimulation at other hours of the day. Among other benefits, device longevity may be increased due to the energy saving of this programming. Thus the stimulators 12 may deliver stimulation pulses for a fraction of each hour while the patient is awake. The  
25 programmability of calendar 48, described below, allows the application of longer-term circadian variations which may likewise be beneficial to the patient and extend battery life.

A plurality of pulse train parameters may be  
30 stored in memory associated with the programmable calendar 48. Sample data 90 for a treatment period is

shown in FIG. 7. The data 90 may be for a 24-hour period, such as "day one" 92, which may include calendar information 94. The pulse trains may be stored as cycles 96. For example, pulse train parameters may include start times 98, stop times 100, 5 the pulsewidth 102, the pulse interval 104, the duration of the applied pulses (the "on" period) 106, or the duration period in which no pulses are applied (the "off" period) 108, and the voltage of the pulse or the pulse height 109. The programmable calendar 48 10 receives data from the clock 46 concerning the time-of-day and the date. Programmable calendar 48 can obtain the associated parameters from the data 90 and supply them the processor 44, accordingly. The "date" associated with the treatment may vary, depending on 15 the expected duration of the treatment. For example, in data format 110 (FIG. 8), the data may correspond to the day of week (e.g., "day one" 112 through "day seven" 114). Each of the data points in day one 112 through day seven is similar to data point 90. The 20 programmable calendar 48 may function on a seven-day cycle wherein programmable calendar accesses day one after day seven in a continuous loop 116. Thus, each day of the week could have a particular sequence of stimulating pulse train parameters. As a result, the 25 pulse train is programmed to stimulate the stomach tissue in the same way on the same day of each week.

As illustrated in FIG. 9, the data format 120 may refer to a simple, numbered day in a periodic sequence of days, such as the numbered days of the year 30 (i.e., "day one" 122 through day 365" 124), or the numbered days within a month (e.g., "day one" 112

through "day 31", not shown). The calendar 48 would then cycle back to the first data point as indicated by arrow 126. As illustrated in FIG. 10, the data format 130 may be hierarchical and thus may recognize intermediate time periods, such as weeks 132 and/or 5 months (not shown) within a treatment period. For example, it may recognize that the treatment is at "week two" 134 or "week three" 136, in addition to the elapsed number of days. The calendar 48 could be programmed to so that the pulse generator 10 is turned 10 off for a number of weeks. The generator may then be turned on one day a week, During the next week, the generator may be turned on for two days a week, etc. Each sequence of cycles (see, FIG. 7) within a given "on" day, could also be different from the previous 15 "on" day.

The programmability of the pulse train wave forms based on the date provides the ability to turn the above stimulating pulse train on or off or increase or decrease waveform parameters over increasingly 20 longer meshed periods of time.

An alternative embodiment of the neuromuscular stimulator described above includes an additional mode for stimulating the neuromuscular tissue of the gastrointestinal tract. The 25 neuromuscular stimulator applies a series of primary electrical pulses to the tissue as described hereinabove. These electrical pulses may be applied during a first time interval, and may be discontinued during a second time interval. A secondary series of 30 pulses having a lower voltage may be applied to the tissue during the second time interval, i.e., when the

Data, including, for example, sensed current, may be measured. The current data may be analyzed for changes over time. From this analysis, statistics may be computed. For example, a statistic which may be computed is the time period in which the changes in the current data repeats. This time period may be used to approximate the peristaltic action of the tissue. It may be desirable to change the rate of peristaltic activity, i.e., to slow down or increase the rate thereof, by varying the series of electrical pulses based on the statistics as described above.

The foregoing is merely illustrative of the  
15 principles of this invention and various modifications  
can be made by those skilled in the art without  
departing from the scope and spirit of the invention.

What is Claimed is:

1. A neuromuscular stimulator for stimulating tissue of the gastrointestinal tract by applying a current-controlled electrical pulse to the neuromuscular tissue, comprising:

5 a voltage sensor to detect a voltage across the neuromuscular tissue being stimulated; and circuitry configured to compare the voltage with a predetermined voltage threshold and to adjust the current-controlled pulse if the voltage is  
10 found to meet the predetermined voltage threshold, such that the voltage does not exceed the predetermined voltage threshold.

2. The neuromuscular stimulator defined in  
15 claim 1, wherein the voltage threshold is adjustable.

3. The neuromuscular stimulator defined in claim 1, wherein the circuitry is configured to set the voltage threshold based on a current level associated with the current-controlled pulse.

20 4. The neuromuscular stimulator defined in claim 3, wherein the circuitry is configured to prepare a set of voltage thresholds and associated respective current levels.

5. The neuromuscular stimulator defined in  
25 claim 1, wherein the circuitry is configured to calculate electrode resistance, said electrode

resistance being voltage limit value divided by current value.

6. The neuromuscular stimulator defined in claim 5, wherein the circuitry is configured to determine an increment of adjustment of voltage based  
5 on the electrode resistance.

7. The neuromuscular stimulator defined in claim 5, wherein the circuitry is configured to associate the electrode resistance with the current level of the current-controlled pulse.  
10

8. The neuromuscular stimulator defined in claim 7, further comprising:  
a memory device to store the electrode resistance and the associated current level.  
15

9. The neuromuscular stimulator defined in claim 5, further comprising:  
a display device to display the electrode resistance and the associated current level.

10. The neuromuscular stimulator defined in claim 1, wherein the circuitry is configured to calculate capacitance of said tissue, said capacitance being the ratio of the current and the time rate of change of the voltage during an individual electrical  
25 stimulating pulse.

11. The neuromuscular stimulator defined in claim 10, wherein the circuitry is configured to

determine the increment of adjustment based on the capacitance.

12. The neuromuscular stimulator defined in claim 10, wherein the circuitry is configured to associate the capacitance with the current level of the  
5 current-controlled pulse.

13. The neuromuscular stimulator defined in claim 10, further comprising:  
a memory device to store the capacitance  
10 and the associated current level.

14. The neuromuscular stimulator defined in claim 10, further comprising:  
a display device to display the  
15 capacitance and the associated current level.

15. The neuromuscular stimulator defined in claim 1, further comprising:  
a memory device to store an event  
characterized by the voltage being found to meet the  
20 predetermined voltage threshold.

16. The neuromuscular stimulator defined in claim 1, wherein the neuromuscular stimulator is configured to determine and store a time value during the electrical pulse when the voltage associated with  
25 the electrical pulse meets the predetermined voltage threshold.



17. The neuromuscular stimulator defined in claim 1, wherein the voltage sensor is configured to detect the voltage across the neuromuscular tissue at a leading edge of the electrical pulse.

18. The neuromuscular stimulator defined in  
5 claim 1, wherein the voltage sensor is configured to detect the voltage across the neuromuscular tissue at a trailing edge of the electrical pulse.

19. A method of stimulating neuromuscular tissue of the gastrointestinal tract comprising:  
10                   applying a current-controlled electrical pulse to the neuromuscular tissue to stimulate the neuromuscular tissue;  
                  detecting a voltage across the neuromuscular tissue being stimulated;  
15                   comparing the voltage with a predetermined voltage threshold; and  
                  adjusting the current-controlled pulse if the voltage is found to meet the predetermined voltage threshold by the detecting, such that the  
20 voltage does not exceed the predetermined voltage threshold.

20. The method defined in claim 19, further comprising:  
25                   prior to comparing the voltage with a predetermined voltage threshold, setting the voltage threshold based on a current level associated with the current-controlled pulse.

21. The method defined in claim 20, further comprising:

5 prior to applying the current-controlled pulse to the neuromuscular tissue, preparing a set of voltage thresholds and associated respective current levels.

22. The method defined in claim 21, wherein preparing the set of voltage thresholds comprises:

10 setting a test value for the voltage threshold;  
applying a first current pulse to the tissue to be stimulated;  
iteratively varying the test value until the voltage level across the tissue is found to meet the test value; and  
15 associating the voltage level with the respective current level in the set of voltage thresholds.

23. The method defined in claim 22, wherein preparing the set of voltage thresholds further  
20 comprises:

before the step of associating, multiplying the measured voltage level by a factor selected from a range between about 1.0 and 1.5.

24. The method defined in claim 19, further  
25 comprising:

after applying the current-controlled pulse to the neuromuscular tissue, calculating

electrode resistance, said electrode resistance being voltage limit value divided by current value.

25. The method defined in claim 24, wherein the step of adjusting the current-controlled pulse further comprises:

5                   determining an increment of adjustment of voltage based on the electrode resistance.

26. The method defined in claim 24, further comprising:

                  after calculating the electrode  
10 resistance, associating the electrode resistance with the current level of the current-controlled pulse.

27. The method defined in claim 26, further comprising:

15                   after the step of associating the electrode resistance with the current level of the current-controlled pulse, storing the electrode resistance and the associated current level in a database.

20

28. The method defined in claim 24, further comprising:

                  after the step of associating the electrode resistance with the current level of the  
25 current-controlled pulse, displaying the electrode resistance and the associated current level.

29. The method defined in claim 19, further comprising:

after the step of applying a current-controlled pulse to the neuromuscular tissue, calculating capacitance of said tissue, said capacitance being the ratio of the current and the time rate of change of the voltage.

5                   30. The method defined in claim 29, wherein the step of adjusting the current-controlled pulse further comprises:

                  determining the increment of adjustment based on the capacitance.

10                   31. The method defined in claim 29, further comprising:

                  after the step of calculating the capacitance, associating the capacitance with the current level of the current-controlled pulse.

15                   32. The method defined in claim 29, further comprising:

                  after the step of associating the capacitance with the current level of the current-controlled pulse, storing the capacitance and the associated current level in a database.

                  33. The method defined in claim 29, further comprising:

25                   after the step of associating the capacitance with the current level of the current-controlled pulse, displaying the capacitance and the associated current level.

34. The method defined in claim 19, further comprising:

storing an event in memory characterized by the voltage being found to exceed the predetermined voltage threshold.

5           35. The method defined in claim 19, wherein the detecting a voltage across the neuromuscular tissue being stimulated comprises detecting the voltage at a leading edge of the electrical pulse.

10           36. The method defined in claim 19, wherein the detecting the voltage across the neuromuscular tissue being stimulated comprises detecting the voltage at a trailing edge of the electrical pulse.

15           37. A neuromuscular stimulator for stimulating tissue of the gastrointestinal tract by applying a voltage-controlled electrical pulse to the neuromuscular tissue, comprising:

a current sensor to detect the current applied to the neuromuscular tissue being stimulated; and

20           circuitry configured to compare the current with a predetermined current threshold and to adjust the voltage-controlled pulse if the current is found to meet the predetermined current threshold by the detecting, such that the current does not exceed  
25 the predetermined current threshold.

38. A method of stimulating neuromuscular tissue of the gastrointestinal tract comprising:

applying a voltage-controlled electrical pulse to the neuromuscular tissue to stimulate the neuromuscular tissue;

detecting a current through the neuromuscular tissue being stimulated;

5 comparing the current with a predetermined current threshold; and

adjusting the voltage-controlled pulse if the current is found to meet the predetermined current threshold by the detecting, such that the  
10 current does not exceed the predetermined current threshold.

39. A neuromuscular stimulator for stimulating tissue of the gastrointestinal tract with a series of electrical pulses applied to the  
15 neuromuscular tissue during a treatment period, comprising:

a real time clock configured to supply data corresponding to the time of day during the treatment period;

20 a programmable calendar configured to store a parameter for defining said series of electrical pulses, the parameter having a reference to a respective time of day during the treatment period;

a control circuit configured to apply  
25 said series of electrical pulses defined by the parameter at the respective time of day.

40. The neuromuscular stimulator defined in claim 39, wherein the parameter is a time period during

which said series of electrical pulses are applied to the neuromuscular tissue.

41. The neuromuscular stimulator defined in claim 40, wherein the time period comprises a start time with reference to the time of day and a duration  
5 with respect to the start time, and wherein the control circuit is configured to apply the series of electrical pulses beginning at the start time and extending for the duration.

42. The neuromuscular stimulator defined in  
10 claim 40, wherein the time period comprises a start time with reference to the time of day, a first duration with respect to the start time, and a second duration with respect to the first duration, and  
15 wherein the control circuit is configured to apply the series of electrical pulses beginning at the start time and continuing for the first duration, and discontinuing the series of electrical pulses during the second duration.

43. The neuromuscular stimulator defined in  
20 claim 40, wherein the time period comprises a first time with reference to the time of day and a second time with reference to the time of day, and wherein the control circuit is configured to apply the series of electrical pulses beginning at the first time and  
25 discontinuing the series of electrical pulses at the second time.

5           45. The neuromuscular stimulator defined in  
claim 39, wherein the parameter is a time period  
corresponding to the pulse interval between each pulse  
in the series of electrical pulses.

10           46. The neuromuscular stimulator defined in  
claim 39, wherein the parameter is a voltage  
corresponding to the pulse height for each pulse in the  
series of electrical pulses.

15           47. The neuromuscular stimulator defined in  
claim 39, wherein the real time clock is configured to  
supply data corresponding to a week during said  
treatment period.

20           48. The neuromuscular stimulator defined in  
claim 39, wherein the real time clock is configured to  
supply data corresponding to a day of the week during  
said treatment period.

25           49. The neuromuscular stimulator defined in  
claim 39, wherein the real time clock is configured to  
supply data corresponding to the month of the year  
during said treatment period.

          50. The neuromuscular stimulator defined in  
claim 49, wherein the real time clock is configured to



supply data corresponding to a day of the month during said treatment period.

51. The neuromuscular stimulator defined in claim 39, wherein the real time clock is configured to supply data corresponding to a day of the year during said treatment period.

52. A method of stimulating neuromuscular tissue of the gastrointestinal tract with a series of electrical pulses applied to the neuromuscular tissue during a treatment period, comprising:

- supplying data corresponding to the time of day during the treatment period;
- storing a parameter for defining said series of electrical pulses, the parameter having a reference to a respective time of day during the treatment period; and
- applying said series of electrical pulses defined by the parameter at the respective time of day.

53. The method defined in claim 49, wherein supplying the time of day comprises:

- providing a real time clock.

54. The method defined in claim 52, wherein storing the parameter further comprises:

- providing a programmable calendar for storing the parameter.

55. The method defined in claim 52, wherein storing the parameter further comprises:

storing the parameter on the programmable calendar.

56. The method defined in claim 52, wherein  
5 the parameter is a time period, and wherein the storing the parameter further comprises:

storing the time period during which said series of electrical pulses are applied to the neuromuscular tissue.

10 57. The method defined in claim 56, wherein the storing the time period comprises:

storing a start time with reference to the time of day, and storing a duration with respect to the start time; and

15 applying the series of electrical pulses beginning at the start time and extending for the duration.

58. The method defined in claim 56, wherein the storing the time period comprises:

20 storing a start time with reference to the time of day, storing a first duration with respect to the start time, and storing a second duration with respect to the first duration; and

25 applying the series of electrical pulses beginning at the start time and continuing for the first duration, and discontinuing the series of electrical pulses during the second duration.

59. The method defined in claim 56, wherein the storing the time period comprises:

storing a first time with reference to the time of day, and storing a second time with reference to the time of day; and

5 applying the series of electrical pulses beginning at the first time and discontinuing the series of electrical pulses at the second time.

60. The method defined in claim 56, wherein the parameter is a time period, and wherein the storing  
10 the parameter further comprises:

storing the time period corresponding to the pulse width for each pulse in the series of electrical pulses.

61. The method defined in claim 56, wherein the parameter is a time period, and wherein the storing  
15 the parameter further comprises:

storing the time period corresponding to the pulse interval between each pulse in the series of  
20 electrical pulses.

62. The method defined in claim 56, wherein the parameter is a voltage, and wherein the storing the parameter further comprises:

25 storing the voltage corresponding to the pulse height for each pulse in the series of electrical pulses.

63. The method defined in claim 49, wherein the supplying data corresponding to the time of day further comprises:

supplying data corresponding to a week during said treatment period.

5

64. The method defined in claim 63, wherein the supplying data corresponding to the time of day further comprises:

supplying data corresponding to a day of the week during said treatment period.

10

65. The method defined in claim 49, wherein the supplying data corresponding to the time of day further comprises:

supplying data corresponding to the month of the year during said treatment period.

15

66. The method defined in claim 65, wherein the supplying data corresponding to the month of the year further comprises:

supplying data corresponding to the day of the month during said treatment period.

20

67. The method defined in claim 49, wherein the supplying data corresponding to the time of day further comprises:

supplying data corresponding to the day of the year during said treatment period.

25

Abstract of the Disclosure

Apparatus and method for stimulating neuromuscular tissue in the stomach. The neuromuscular stimulator stimulates the neuromuscular tissue by applying current-controlled electrical pulses. A voltage sensor  
5 detects the voltage across the neuromuscular tissue to determine if the voltage meets a predetermined voltage threshold. A control circuit adjusts the current-controlled pulse if the voltage is found to meet the voltage threshold, such that the voltage does not  
10 exceed the voltage threshold. A voltage-controlled pulse may also be applied to the tissue. A current sensor would then detect whether the current on the neuromuscular tissue meets a predetermined current threshold, and a control circuit adjusts the voltage-  
15 controlled pulse such that the current does not exceed the current threshold. A real time clock may be provided which supplies data corresponding to the time of day during the treatment period. A programmable calendar stores parameters of the stimulating pulse,  
20 wherein the parameters have a reference to the time of day.

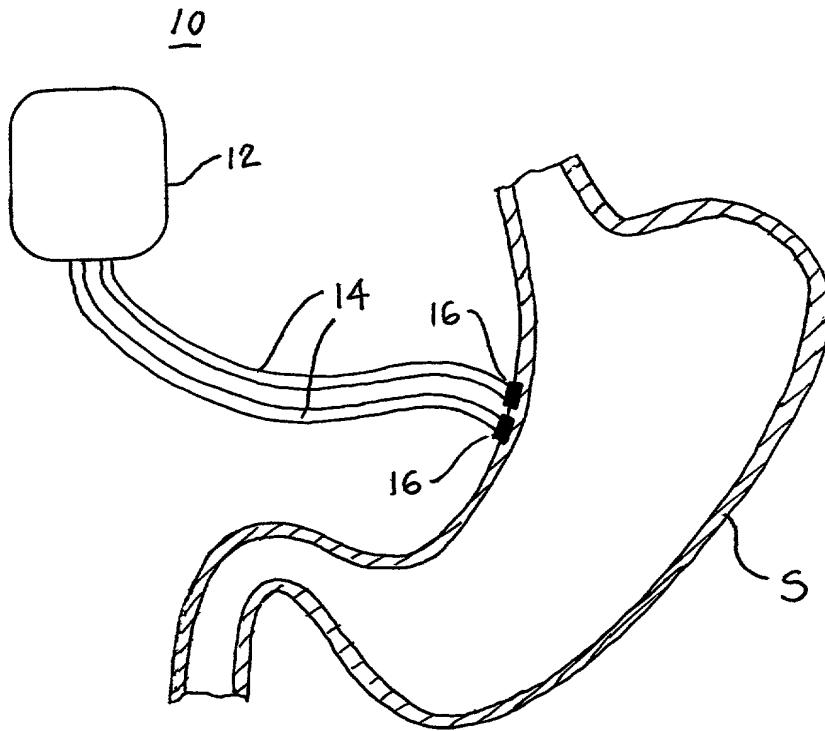


FIG. 1

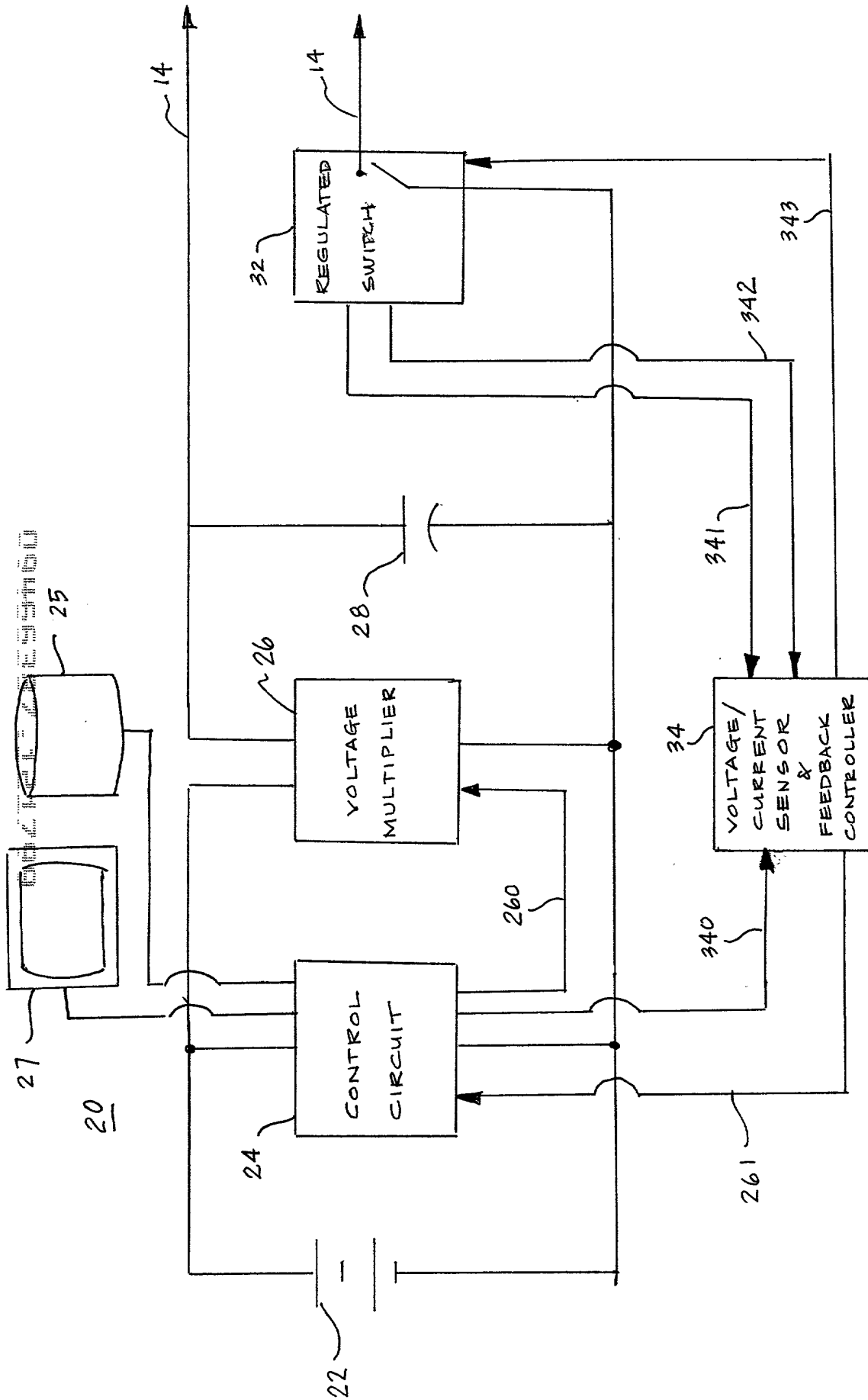


FIG. 2

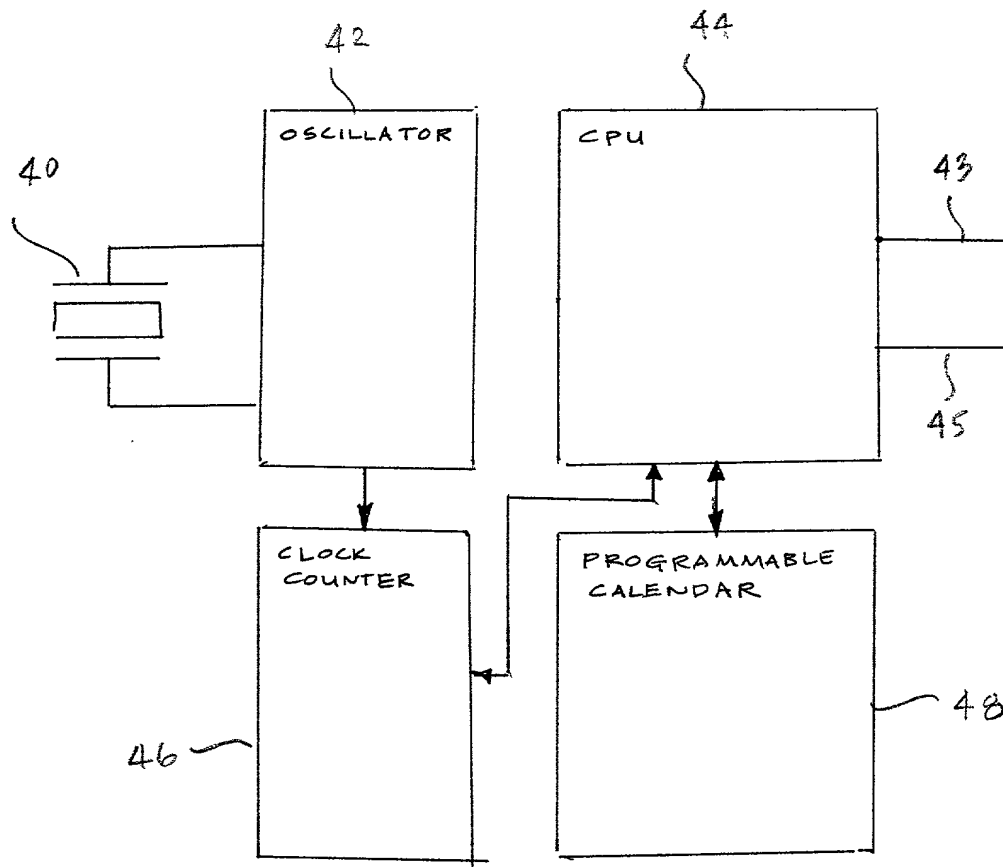


FIG. 3



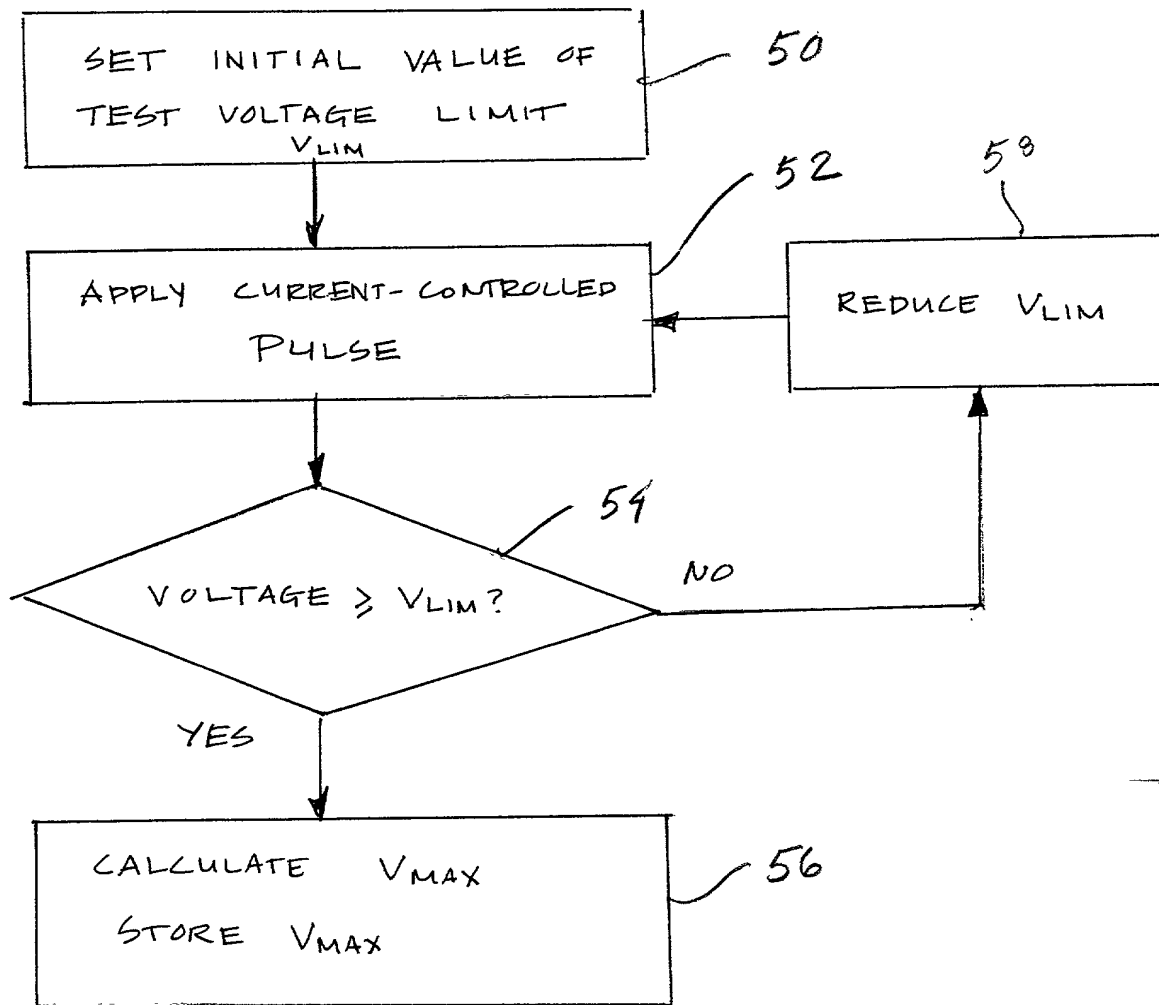


FIG. 4

FIG. 5

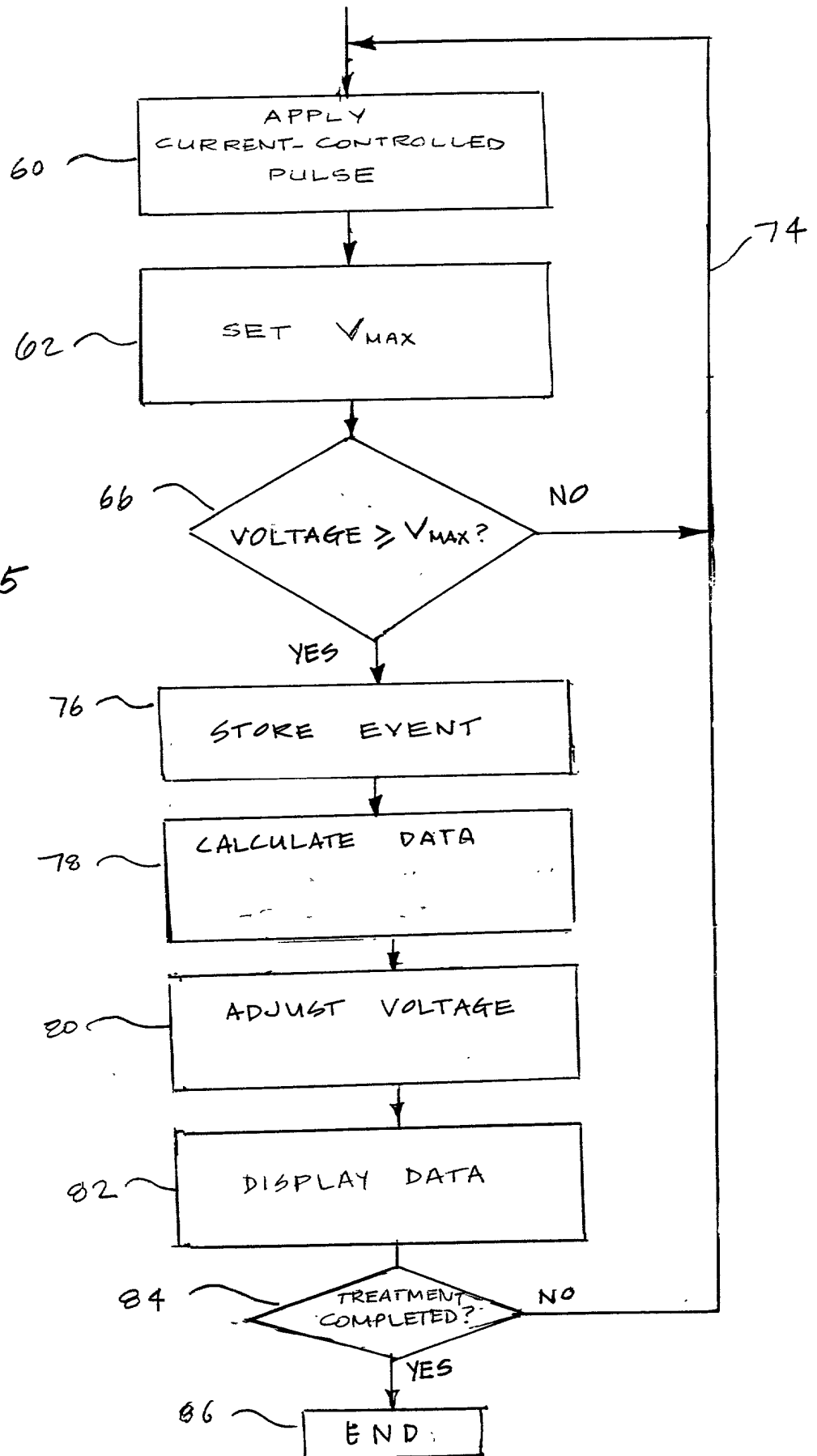


FIG. 6(a)

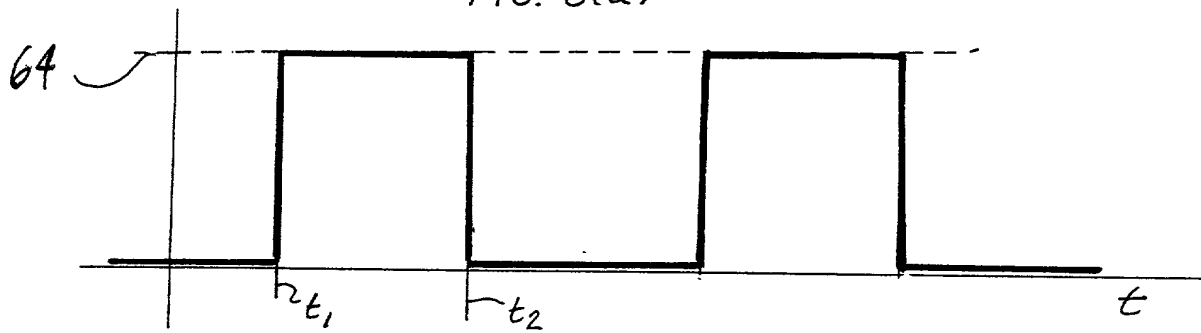


FIG. 6(b)

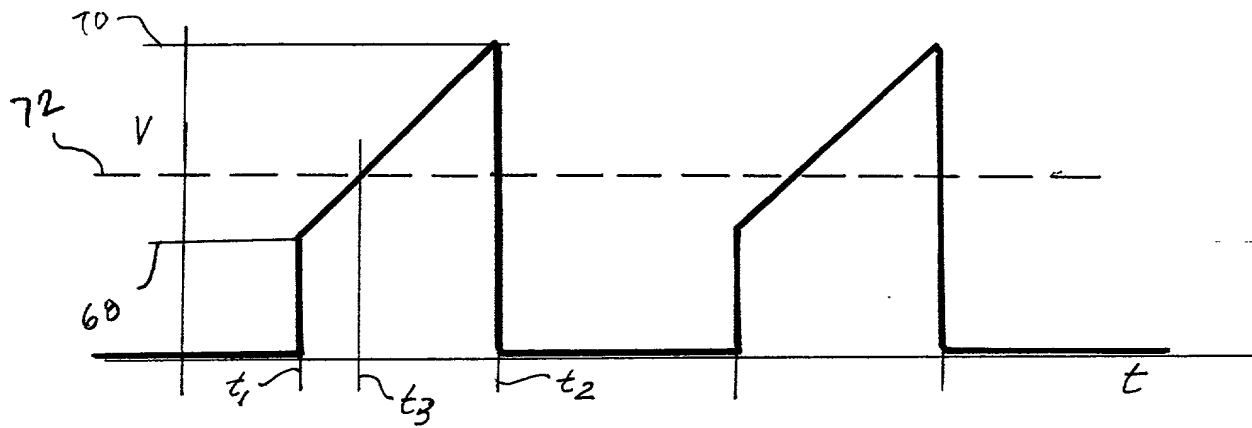
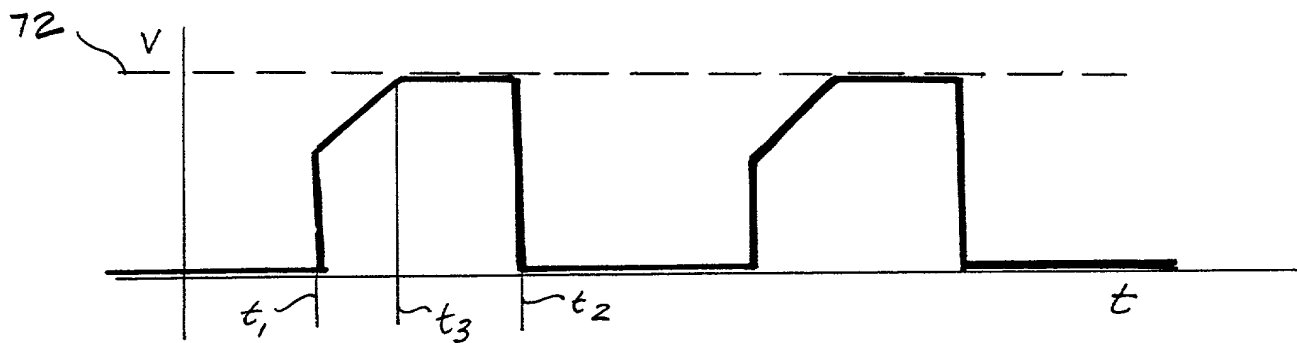


FIG. 6(c)



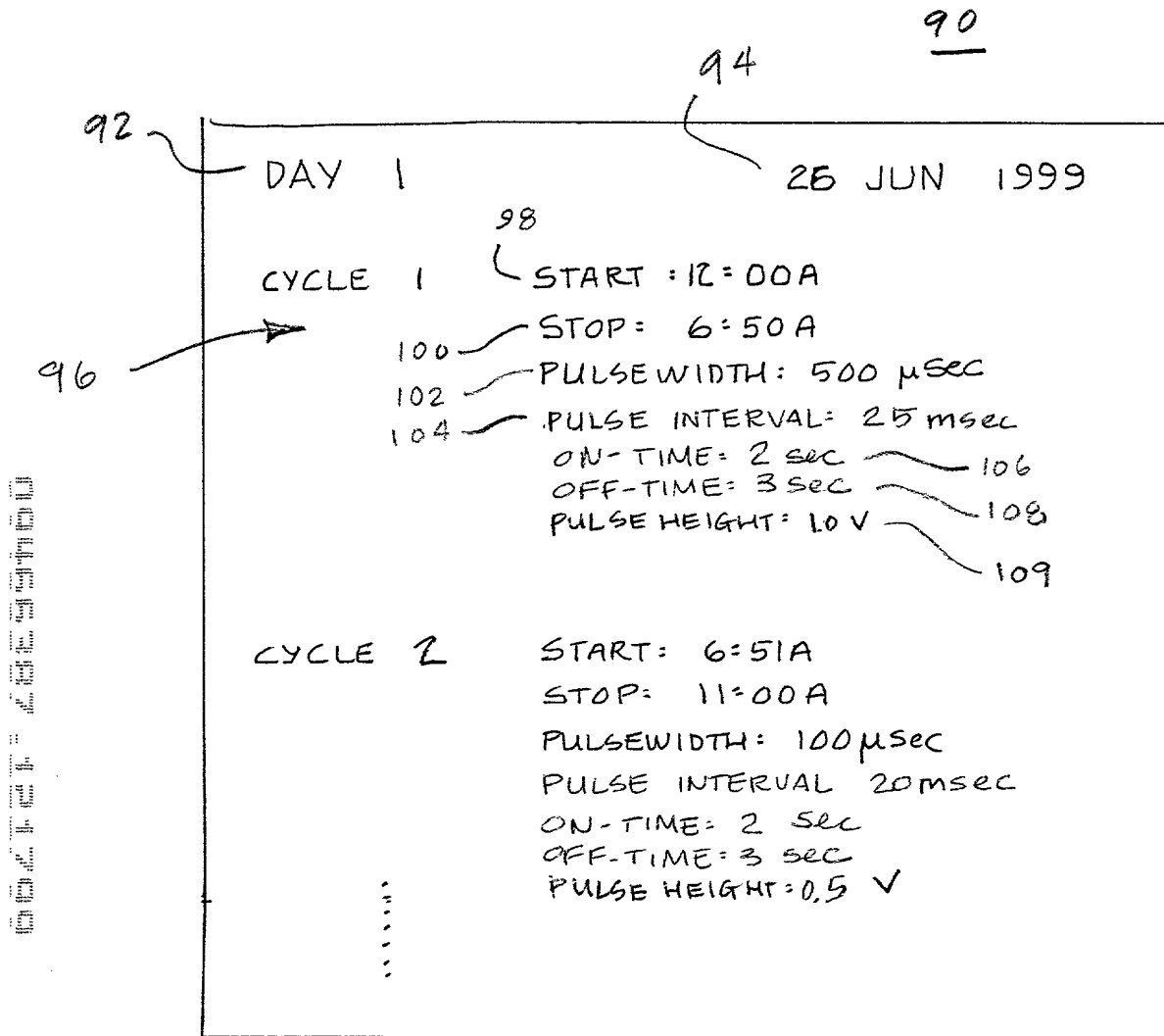


FIG. 7

FIG. 8

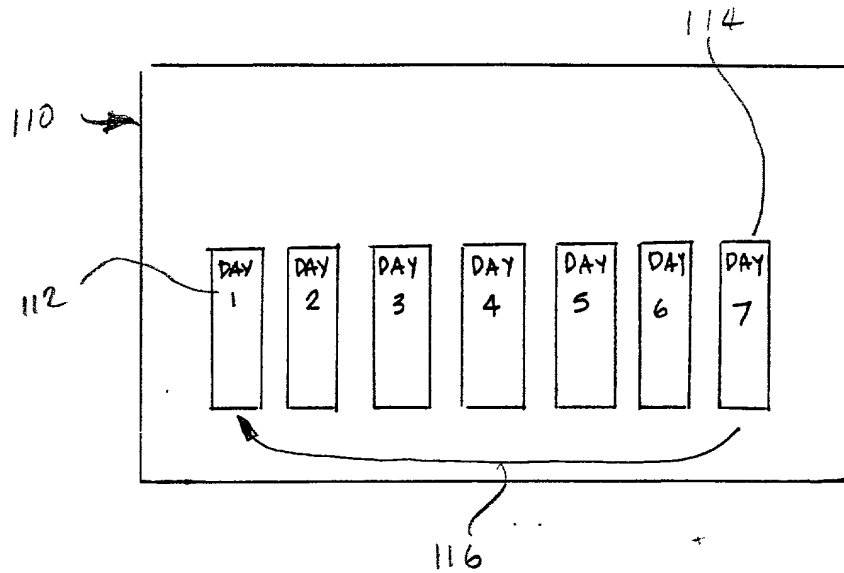
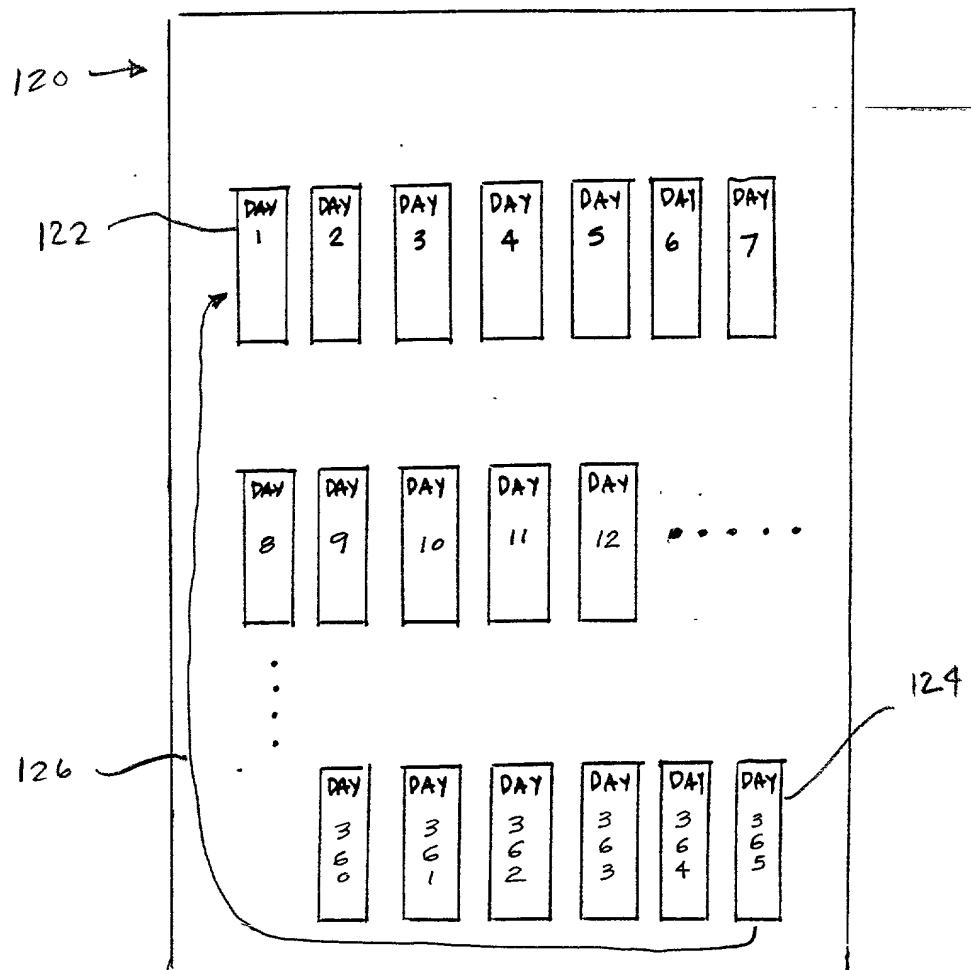
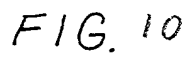


FIG. 9





**DECLARATION AND POWER OF ATTORNEY  
FOR PATENT APPLICATION**

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name;

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

GASTRIC STIMULATOR APPARATUS AND METHOD FOR USE  
the specification of which

(check [X] is attached hereto  
one)

[ ] was filed on \_\_\_\_\_ as  
Application Serial No. \_\_\_\_\_  
and was amended on \_\_\_\_\_.  
(if applicable)

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I do not know and do not believe that the invention was ever patented or described in any printed publication in any country before my or our invention thereof or more than one year prior to this application.

I do not know and do not believe that the invention was in public use or on sale in the United States of America more than one year prior to this application.

I acknowledge the duty to disclose to the United States Patent and Trademark Office all information known by me to be material to patentability as defined in Title 37, Code of Federal Regulations, § 1.56.

I hereby claim foreign priority benefits under Title 35, United States Code, § 119 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or

inventor's certificate having a filing date before that of the application on which priority is claimed:

Prior Foreign Application(s)

			<u>Priority Claimed</u>	
			<u>[ ]</u>	<u>[ ]</u>
<u>(Number)</u>	<u>(Country)</u>	<u>(Day/Month/Year Filed)</u>	Yes	No
<u>(Number)</u>	<u>(Country)</u>	<u>(Day/Month/Year Filed)</u>	<u>[ ]</u>	<u>[ ]</u>
			Yes	No

I hereby claim the benefit under Title 35, United States Code § 119(e) of any United States provisional application(s) listed below:

<u>60/129,209</u>	<u>April 14, 1999</u>
(Provisional Appln. No.)	(Filing Date)
<u>(Provisional Appln. No.)</u>	<u>(Filing Date)</u>

I hereby claim the benefit under Title 35, United States Code, § 120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, § 112, I acknowledge the duty to disclose to the United States Patent and Trademark Office all information known by me to be material to patentability as defined in Title 37, Code of Federal Regulations, § 1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application:

<u>(Application Serial No.)</u>	<u>(Filing Date)</u>	<u>(Status) (patented, pending, abandoned)</u>
<u>(Application Serial No.)</u>	<u>(Filing Date)</u>	<u>(Status) (patented, pending, abandoned)</u>



As a named inventor, I hereby appoint the following attorneys or agents to prosecute this application and transact all business in the United States Patent and Trademark Office connected therewith:

Robert R. Jackson, (Reg. No. 26,183)

Thomas L. Giannetti, (Reg. No. 27,892)

Walter M. Egbert, III (Reg. No. 37,317)

Send correspondence to: Walter M. Egbert, III  
FISH & NEAVE  
1251 Avenue of the Americas  
New York, New York 10020-1104

Direct telephone calls to: Walter M. Egbert, III  
(212) 596-9000

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Full name of first inventor Pat L. Gordon

First Inventor's signature \_\_\_\_\_ Date \_\_\_\_\_

Residence 494 Highcroft Road

Citizenship USA

Post Office Address 494 Highcroft Road

Wyzata, MN 55391